I. Claims 1-20, 25-28, drawn to methods for treating ischemic-reperfusion conditions with Factor IXa compounds, classified in Class 424, subclass 130.1 and Class 514, subclass 8 or 44.

II. Claims 21-24, drawn to methods of identifying compounds that are capable of improving ischemic disorders, classified in Class 51, subclass 8.

III. Claims 29-30, drawn to methods of inhibiting clot formation with muteins, classified in Class 514, subclass 8.

IV. Claims 31-32, drawn to methods of monitoring the effects of Factor IXa on ischemic disorders, classified in Class 600, subclass 407.

The Examiner stated that inventions I/II/III/IV are different methods requiring different reagents, methods steps and endpoints. The Examiner stated that therefor they are patentably distinct.

The Examiner stated that because these inventions are distinct for the reasons given above and the search required for any group from Groups I-IV is not required for any other group from Groups I-IV and Groups I-IV have acquired a separate status in the art as shown since the searches are not co-extensive and encompass divergent subject matter, restriction for examination purposes as indicated is proper.

The Examiner stated that this application contains claims directed to the following patentably distinct species of the claimed Groups I/II/III/IV: wherein the Factor IX compound is: A) a peptide or a mutated peptide, B) a peptiodomimetic, C) a nucleic acid or a

mutated nucleic acid, D) a small molecule, E) a mutein or F) an antibody or fragment thereof.

The Examiner stated that these species are distinct because their structures and modes of action are different.

The Examiner stated that applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. The Examiner stated that currently, claims 1, 21, 29 and 31 are generic.

In response to this restriction requirement, applicants hereby elect, with traverse, to prosecute the invention of Examiner's Group III, claims 29-30 drawn to methods of inhibiting clot formation with muteins.

However, applicants request that the restriction of Examiner's Group I from Examiner's Groups II-IV be withdrawn in view of the fact that the claims of Examiner's Group I are not independent of Examiner's Group II-IV. Applicants note that 35 U.S.C. §121 states, in part, that "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." [Emphasis added].

Under M.P.E.P. §802.01, "independent" means "there is no disclosed relationship between the subjects disclosed, that is, they are unconnected in design, operation and effect." The claims of Examiner's Group III, drawn to methods of inhibiting clot formation with muteins are related to the claims of Examiner's Groups I-II and IV, which are drawn to methods for treating ischemic-

reperfusion conditions with Factor IXa compounds (claims 1-20 and 25-28), methods of identifying compounds that are capable of improving ischemic disorders, methods of identifying compounds that are capable of improving ischemic disorders (claims 21-24), and methods of monitoring the effects of Factor IXa on ischemic disorders (claims 31-32), respectively, since the claimed methods all relate to ischemic conditions and disorders. Applicants therefore maintain that the claims of Groups I and II-IV are related and that Groups I and II-IV are not independent. Accordingly, restriction is not proper.

Applicants therefore respectfully assert that two or more independent and distinct inventions have not been claimed in the subject application because the groups are not independent under M.P.E.P. §802.01. Therefore, restriction is improper under 35 U.S.C. §121.

Additionally, applicants point out that M.P.E.P. §803, the Examiner must examine the application on the merits, even though it includes claims to distinct inventions, if the search and examination of an application can be made without serious burden. There are two criteria for a proper requirement for restriction, namely (1) the invention must be independent and distinct; AND (2) there must be a serious burden on the Examiner if restriction is not required.

Applicants maintain that there would not be a serious burden on the Examiner if restriction were not required. A search of prior art with regard to Group III, will reveal whether any prior art exists as to the subject matter defined by claims in any one of Groups I, II, and IV. Since there is no burden on the Examiner to examine Groups I-IV in the subject application, the Examiner must examine the entire application on the merits.

Applicants maintain that claims 1-32 define a single inventive concept. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw the restriction requirement and examine claims 1-32 on the merits.

If a telephone conference would be of assistance in advancing the prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone at the number provided below.

No fee, except the enclosed $55.00 fee for a one-month extension of time, is deemed necessary in connection with the filing of this Communication. If any additional fees are required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

7/27/99
John P. White Date
Reg. No. 28,678